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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,683	01/22/2002	Lloyd J. Old	L0461/7125	5148

23628 7590 01/14/2005

WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,683

Applicant(s)

OLD ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 16-28, 32-73 and 79-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15, 29-31 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/6/03, 9/22/03</u> | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group XIV in the reply filed on 11/03/2004 is acknowledged.

Claims 1-11, 20-28, 32-73, 79-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 16-19 are also withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, as discussed over the telephone interview conducted on 01/12/2005 with applicant's representative Mr. John Van Amsterdam. The Restriction Requirement mailed on 10/06/2004 at page 4 included claims 16-19, drawn to cell expressing the CT antigen in the elected group. However, claims 16-19 belong to group XIII in the Restriction Requirement mailed on 10/06/2004 at page 4.

Claims 1-82 are pending. Claims 12-15, 29-31, and 74-78 are examined as they are drawn to pharmaceutical comprising the polypeptide encoded by SEQ ID NO:18 nucleic acid as the active ingredient.

Claim Objections

Claims 13, 14, 29, 30, and 74-78 are objected to because of the following informalities: The claims contain multiple inventions. The claims have not been amended to reflect the election. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12, 14, and 15 are interpreted as drawn to pharmaceutical comprising a genus of agents.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the only factor present in the claims 12, 14, and 15 are functional characteristics (i.e. enriches selectively the presence of complexes of an HLA molecules and a human CT antigen peptide) of the claimed genus of agents. There is not even identification of any particular portion of the structure that must be conserved in order to have the recited function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. For claim 14, "the human CT antigen peptide" also lacks written description because the specification, especially at abstract and sequence listing teaches that CT antigen peptide is a group of proteins that are expressed in tumors and testis but the structures are not related. For example, SEQ ID NO:19, 21, and 23 do not share any structural similarities. Therefore, "the human CT antigen peptide" is mere functional description of a genus of proteins and the claim does not describe any structure associated with the function.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of agents, given that the specification has only described 19 protein. Therefore, only SEQ ID NO:19 polypeptide encoded by SEQ ID NO:18 nucleic

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acid but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-15, 29-31, and 74-77 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. 5935578 A (Aug. 10, 1999).

Claims 12-15, 29-31, and 74-78 are interpreted as drawn to a pharmaceutical comprising a polypeptide encoded by SEQ ID NO:19, and pharmaceutically acceptable carrier for intended use of generating T cell medicated response along with an HLA molecule (claims 12-15, 29-31) or one or more of MHC molecules presented on the surface of non-testis cells (claims 74-78), wherein an adjuvant is further comprised in claims 30 and 77.

US Pat. 5935578 A teaches SEQ ID NO:8 (PH30 beta chain sperm protein), a 734 amino acid residue protein that matches 100 % to instant SEQ ID NO:19 encoded by instant SEQ ID NO:18. Note Exhibit A (sequence alignment of instant SEQ ID NO:19 protein against SEQ ID NO:8 of US Pat. 5935578 A). US Pat. 5935578 A at column 2, lines 57-66 teaches composition comprising at least one epitope from the newly discovered human protein in a “pharmaceutically acceptable carrier”. US Pat. 5935578 also teaches at Example 3, column 12, lines 24-27 a vaccine preparation, i.e.

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"The affinity-purified PH30 beta, in 0.375 ml phosphate-buffered saline (PBS) containing 3 mM octylglucoside (OG) is emulsified with 0.375 ml complete Freund's adjuvant (CFA)." Thus, the protein of US Pat. 5935578 A is in a pharmaceutically acceptable carrier and adjuvant.

The preamble recitation of "pharmaceutical preparation for a human subject" is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the composition comprising the polypeptide as the main active ingredient *per se*.

Although US Pat. 5935578 does not teach whether the human PH30 beta chain sperm protein could form a complexes of HLA or any other MHC molecules presented on the surface of non-testis cells when administered to a human subject, it is the Office position that the protein of the art meets that limitation of the instant claims because the structure of the proteins are the same and must possess the same function if they are identical structures.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed composition. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 74, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. 5,935,578 A (Aug. 10, 1999) in view of US 5,961,979 A (October 5, 1999).

Claims 74, 77, and 78 are interpreted as drawn to a composition comprising SEQ ID NO:19 and saponins as an adjuvant.

US Pat. 5935578 A teaches a protein identical to instant SEQ ID NO:19, and adjuvant. Note the 102 (b) rejection above for further details.

US Pat. 5935578 A does not specifically teach those adjuvant species listed in the instant claims 78.

However, US 5961979 A teaches at column 23 line 24 that saponins are well known adjuvant commonly used in the art to stimulate immune response.

Therefore, it would have been obvious and motivated to use saponins as an adjuvant with reasonable expectation of success for non-specific immunostimulator effect since the art knows how to make and use saponins as an adjuvant in a vaccine.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

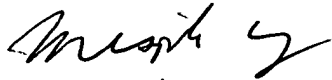
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272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642


MISOOK YU
PATENT EXAMINER

GenCore version 5.1.6
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OM protein - protein search, using sw model

Run on: January 10, 2005, 22:09:32 : Search time 40 Seconds
(without alignments)
1216.935 Million cell updates/sec

Title: US-10-054-683-19

Perfect score: 3984

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Scoring table: BLOSUM62

Gapop 10.0, Gapext 0.5

Searched: 478139 seqs, 66318000 residues

Total number of hits satisfying chosen parameters: 478139

Minimum DB seq length: 0
Maximum DB seq length: 200000000

Post-processing: Minimum Match 0%

Maximum Match 100%

Database:

Issued Patents AA:*

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- 2: /cgn2_6/ptodata/1/1aa/5B.COMB.pep:*
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- 5: /cgn2_6/ptodata/1/1aa/PTUS.COMB.pep:*
- 6: /cgn2_6/ptodata/1/1aa/backfile1.pep:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

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4	3551	89.1	651	2	US-08-765-243-2
5	3551	89.1	651	5	PCT-US95-07295-2
6	2440	61.2	735	2	US-08-765-243-6
7	2440	61.2	735	2	US-08-765-243-6
8	1512	38.0	457	1	US-08-264-101-4
9	1512	38.0	457	2	US-08-765-243-4
10	1512	38.0	457	5	PCT-US95-07295-4
11	1506.5	37.8	787	4	US-10-000-489-70
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ALIGNMENTS

RESULT 1
US-08-765-243-8
Sequence 8, Application US/08765243
Patent No. 5935578
GENERAL INFORMATION:
APPLICANT: ALVES, KENNETH
APPLICANT: GUPTA, SUNIL K.
APPLICANT: HOLDS, GREGORY F.
TITLE OF INVENTION: CONTRACEPTIVE VACCINE
NUMBER OF SEQUENCES: 8
CORRESPONDENCE ADDRESS:
ADDRESSEE: MARY A. APOLLINA
STREET: P.O. BOX 2000, 126 E. LINCOLN AVENUE
CITY: RAHWAY
STATE: NJ
COUNTRY: USA
ZIP: 07065
COMPUTER READABLE FORM:
MEDIUM TYPE: Floppy disk
COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
SOFTWARE: Patent Release #1.0, Version #1.30
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/765,243
FILING DATE:
CLASSIFICATION: 536
ATTORNEY/AGENT INFORMATION:
NAME: APOLLINA, MARY A
REGISTRATION NUMBER: 34,087
REFERENCE/DOCKET NUMBER: 19244Y
TELECOMMUNICATION INFORMATION:
TELEPHONE: (908) 594-3462
TELEFAX: (908) 594-4720
INFORMATION FOR SEQ ID NO: 8:
SEQUENCE CHARACTERISTICS:
LENGTH: 734 amino acids
TYPE: amino acid
TOPOLOGY: linear
MOLECULE TYPE: protein
US-08-765-243-8
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Best Local Similarity 100.0%; Pred. No. 0;
Matches 734; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
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Exhibit A

Page 2 of 2

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Qy 721 SSDEQPESESEBPKG 734
Db 721 SSDEQPESESEBPKG 734

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NAME: APPOLLINA, MARY A
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REFERENCE/DOCKET NUMBER: 19244Y
TELEPHONE: (908)594-3462
TELEFAX: (908)594-4720
INFORMATION FOR SEQ ID NO: 8:
SEQUENCE CHARACTERISTICS:
LENGTH: 734 amino acids
TYPE: amino acid
TOPOLOGY: linear
MOLECULAR TYPE: protein
PCT-US95-07295-8

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Best Local Similarity 100.0%; Pred. No. 0;
Matches 734; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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601 RNORCVSSSYLGIDCTTDKCNDRGVCKNKKCHCASASTLPDCSVQSDLPFGSIDSQNF 660
661 PPVALPAPLPERRYENIYHSKPMKMPFLPFILPFILCVLAIAMVKNFQKRRTEY 720
661 PPVALPAPLPERRYENIYHSKPMKMPFLPFILPFILCVLAIAMVKNFQKRRTEY 720
721 SSDEQPESESEBPKG 734
721 SSDEQPESESEBPKG 734

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RESULT 3